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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM12/0221

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EXAMINER	
[illegible]	
ART UNIT	**PAPER NUMBER**
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DATE MAILED: 02/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action	Application No. 09/265,606	Applicant(s) ZIMMERMANN ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 January 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search. (see NOTE below);

   (b) ☐ they raise the issue of new matter. (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

4. ☐ Applicant's reply has overcome the following rejection(s): _____.

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

6. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *5 and 16-19*.

   Claim(s) withdrawn from consideration: _____.

9. ☐ The proposed drawing correction filed on _____ a)☐has b)☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

11. ☒ Other: *See attached Interview Summary*

Continuation of 6. does NOT place the application in condition for allowance because: although applicant has set forth a utility for the complete FAPalpha protein (monomer or dimer), applicant has not set forth nor demonstrated a similar utility for a fusion protein containing only the catalytic domain of FAPalpha. It is well known in the art that protein folding (i.e. tertiary structure) is dependent on the amino acid sequence, and as previously set forth, evidence from a similar protein (DDPIV) indicates that the catalytic domain would be internal in the structure of full length, normally folded FAPalpha, and would thus not be expected to comprise eptitopes normally recognized by antibodies to the full length protein. Applicant's claimed fusion protein contains sequences other than FAPalpha, and would therefore be expected to fold and behave differently than FAPalpha. Neither the folding or bahavior of full length FAPalpha, nor of an excised portion (e.g. the catalytic domain alone) is necessarily predictive of the folding and behavior of a fusion protein. As the sequences representing the catalytic domain are present in a larger amino acid sequence different from that of FAPalpha, the structure and activity (if any) of the catalytic domain are unpredictable. While an antibody can certainly be raised to the fusion protein, one skilled in the art would not know, or be able to predict without an undue amount of experimentation, whether those antibodies would recognize FAPalpha itself, or would have activity (e.g. in terms of binding to or inhibiting an "active site") similar to that displayed by antibodies to full-length FAPalpha. The argument that the catalytic domain (alone) is of sufficient size to be immunogenic is not relevant as the claims recite a fusion protein, and no substantial or well established utility has been set forth for the fusion protein. For the reasons previously set forth and set forth above, the rejection under 35 USC 101 is maintained. Although applicant has asserted in the response filed 7/10/00 that the catalytic domain consists of specific amino acid residues, such a teaching is not found anywhere in the originally filed specification or claims. Therefore, based on the teachings of the instant specification, one skilled in the art would not know which residues consitute the catalytic domain, and would not know how to make the claimed fusion protein. As the claimed invention is not enabled by the instant specification, the rejection under 35 USC 112 is maintained .

Marianne P. Allen

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